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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,817	11/08/2000	Jose Remacle	VANM160.001A	2892

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,817

Applicant(s)

REMACLE, JOSE

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-63 is/are pending in the application.
- 4a) Of the above claim(s) 31-33 and 49-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30 and 34-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I and species where in the capture and target molecules are nucleotide sequences (claims 30 and 34-48) in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 31-33 and 49-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claim Rejections - 35 USC § 112

3. Claims 30 and 34-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting, through direct hybridization, DNA that had been spotted onto CD whose surface was first carboxylated and then aminated, does not reasonably provide enablement for:
 - a. The detection of any number of samples of DNA or RNA on a CD support,
 - b. The use of radiation, magnetic fields, "chemo, bio, fluoro, radioactivity, electroluminescence light, radiation",
 - c. The corrosion of one or more layers of the disc,
 - d. The use of one or more microbeads or magnetic particles,
 - e. Where the disc comprises "micro-channels connected and in fluid contact" nor

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- f. Where binary registration data is on the disc or the use of said data in the
“treatment and the interpretation of the signal.”

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Quantity of Experimentation Necessary

The quantity of experimentation need is great, on the order of several man-years and then with little, if any, reasonable expectation of success.

The Amount of Direction or Guidance Provided

The amount of guidance provided is extremely limited.

The Presence or Absence of Working Examples

The specification provides five examples of which only examples 1 and 2 relate to the claimed invention. In Example 1 (pages 26-28) a capture probe was immobilized to aminated polycarbonate on the surface of a CD. The capture probe was either CMV or HIV DNA. The capture probe was allowed to form a duplex structure with biotinylated CMV DNA. Detection

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was achieved through the use of streptavidin-peroxidase which will complex with the biotin, and a TMB solution which, when reacted with peroxidase, will produce a blue color. In example 2, the same protocol was followed except that detection was achieved via the deposition of silver precipitate. The silver precipitate was produced via the utilization of "Solution A and B from Silver enhancement kit (Sigma, St. Louis, USA)." Page 28 teaches that the CD was subsequently "recovered with a gold layer to allow a laser CD player to read information written on the CD and to read the interference due to silver precipitate" (specification at page 28).

The Nature of the Invention

The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The State of the Prior Art

The state of the art, as it relates to the use of CD or DVD systems for nucleic acid chemistries, is in the early developmental stages.

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The Relative Skill of Those in the Art

The relative skill of those in the art that is most closely associated with the claimed invention is high, on par with those that hold a Ph.D. in biochemistry.

The Predictability or Unpredictability of the Art

The invention relates directly to the performance of chemical and enzymatic reactions. Chemical reactions are recognized as being highly unpredictable and therefore require greater levels of disclosure. The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The Breadth of Scope of the Claims

The claims have sufficient bread of scope so to encompass the detection of virtually an and all manner of "target molecules" where virtually any number of target molecules could be detected simultaneously. The claimed method also has sufficient breadth of scope so to encompass the use of any size, mass, and shape of "micro-particle." It is noted that the disc is to comprise these micro-particles and it to somehow be read by at least one optical source. The claims do not recite any means for retaining the particles. It stands to reason that the micro--particles could easily be discharged from the surface of the disc upon the spinning of the disc at a

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high rate of speed. Even if the micro-particles are not removed completely, the movement of the micro-particles from one region to that of another could easily result in the corruption of data obtained from having conducted an assay on said disc.

The claims clearly contemplate the use of fluid communicating means, i.e., a series of channels. The specification is essentially silent as to how one is to synthesize such channels, be they open or closed (on or in such a disc), much less teach in detail how oligonucleotides are to be synthesized therein/thereon.

By not disclosing in such full and complete terms, the skilled artisan would have to resort to trial and error testing so to determine just how the various explicit embodiments contemplated by the claims are to be practiced. Said skilled artisan would clearly have to endeavor for a considerable amount of time, on the order of many man-years, so to be able to practice the full scope of the invention. While some experimentation is permitted, the level of experimentation required to practice the full scope of the claimed invention rises to the level of undue experimentation. Accordingly, and in the absence of convincing evidence to the contrary, the claims are not enabled for their full scope and as such, applicant is urged to consider narrowing the scope of the claims to where it more closely parallels the level of disclosure provided.

Claim Rejections - 35 USC § 102/103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 30 and 34-48 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Virtanen (US Patent 6,030,581).

10. Virtanen teaches at length the use of a disc in the performance of various nucleic acid assays and that the disc can be read by a CD or DVD reader; column 2. The figures teach explicitly of at least some embodiments comprising channels that are in fluid communication.

11. Column 9 discloses the use of micro-spheres as well as the recording of information onto a portion of the disc wherein said information may relate to the spatial addresses or other information related to the assay. Column 9, fifth paragraph, discloses various detection means, including the use of fluorescent dyes. Column 10 discloses using spectrophotometric assays.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
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BLS
July 31, 2002